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(54) **Reinforced balloon dilatation catheter with slitted exchange sleeve and method.**

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Description

TECHNICAL FIELD

This invention relates to balloon dilatation catheters and more particularly, to a reinforced balloon dilatation catheter having a slitted exchange sleeve and method.

BACKGROUND OF THE INVENTION

There is a need for a balloon dilatation catheter which is provided with a sleeve adjacent its proximal extremity which is adapted to facilitate rapid exchanges of balloon dilatation catheters. Additionally, the limitations in the control of the guide wire utilizing such catheters must be overcome. In particular, the torqueability and the pushability of the guide wire in the catheter must be sufficient because the guide wire may be freefloating through a substantial part of its length. In addition, the pushability in the balloon dilatation catheter in itself must be sufficient.

Reference WO-A-8 603 129 discloses a balloon dilatation catheter adapted to be utilized in connection with a guiding catheter and a guide wire, a flexible elongate tubular member having proximal and distal extremities and having a lumen extending therethrough, an inflatable balloon, means mounting the inflatable balloon to the distal extremity of the tubular member forming liquid-seals with the tubular member, the interior of the inflatable balloon being in communication with the lumen and sleeve-like means extending through the balloon, said sleeve-like means having a guide wire lumen extending therethrough, said sleeve-like means being adapted to receive a guide wire extending therethrough. However, reference WO-A-8 603 129 does not disclose a sleeve-like means extending rearwardly from the balloon and alongside the lumen to proximal extremity distal to the proximal extremity of the tubular member or that the sleeve-like means has a slit extending longitudinally of the same from the proximal extremity of the sleeve to a region adjacent the balloon permitting the guide wire to be removed therefrom.

Reference US-A-4 540 404 discloses a balloon catheter for use with a guiding catheter inserted into a vessel of a patient, a flexible elongated tubular member having proximal and distal extremities and having first and second lumens extending therethrough, a balloon carried by the distal extremity of the ular member and having its interior in communication with the second lumen. Reference US-A-4 540 404 does not disclose that the tubular member is provided with a notch which extends from the exterior of the tubular member into a first lumen with the first notch being positioned proximally of the balloon and a guide wire extending through the notch and into the first lumen and through the distal extremity of the tubular member and extending proximally from the notch from along side the tubular member beyond the proximal extremity of the tubular member.

Two embodiments of the invention provide features not found in the prior art, which features greatly aid in the utility of the invention. In a first embodiment of the invention, a balloon dilatation catheter is adapted to be utilized with a guide wire is provided, and comprises: a flexible elongate tubular member having proximal and distal portions, a lumen extending through said tubular member; an inflatable balloon at the distal portion of said tubular member, the interior of said inflatable balloon being in communication with said lumen; and a sleeve-like means adapted to receive said guide wire therethrough, said sleeve-like means having a proximal opening and said sleeve-like means extending through said balloon to a distal opening in the distal extremity of said tubular member, said catheter characterized by the proximal opening of said sleeve-like means being spaced from the proximal end of the catheter and the sleeve-like means having a slit extending longitudinally from the proximal opening of the sleeve-like means to a region adjacent the balloon to facilitate removal of the guide wire therethrough.

In a second embodiment of the invention, a balloon dilatation catheter for use with a guide wire which is adapted to be inserted into a vessel of a patient is provided which comprises: a flexible elongate tubular member having proximal and distal portions and having a first lumen and a second lumen extending therethrough; and a balloon carried by the distal portion of said tubular member and having its interior in communication with said second lumen; and being characterized by said tubular member being provided with a notch which extends from the exterior of said tubular member into said first lumen, said notch being positioned proximally of said balloon, said guide wire extending through said notch and into said first lumen and through the distal extremity of said tubular member and extending proximally from said notch alongside said tubular member beyond the proximal extremity of said tubular member.

THE DRAWINGS

Figure 1 is a cross-sectional side elevational view of a reinforced balloon dilatation catheter with slitted exchange sleeve incorporating the present invention.

Figure 2 is a cross-sectional view taken along the line 2-2 of Figure 1.

Figure 3 is a cross-sectional view taken along the line 3-3 of Figure 1.

Figure 4 is a cross-sectional view taken along the line 4-4 of Figure 1.

Figure 5 is a cross-sectional view taken along the line 5-5 of Figure 1.

Figure 6 is an enlarged cross-sectional view of a portion of the catheter shown in Figure 1.

Figure 7 is a side elevational view of the reinforcing mandrel which is utilized in the device shown in Figure 1.

DETAILED DESCRIPTION

In general, the reinforced balloon dilatation catheter with slitted exchange sleeve is adapted to be utilized with a guiding catheter inserted into the vessel of the patient. It is comprised of a flexible elongate member with its stiffness decreasing from the proximal extremity to the distal extremity. It is provided with first and second lumens extending therethrough. Inflatable balloon means is provided. Means is provided for securing the inflatable balloon means to the distal extremity of the flexible elongate tubular member with the interior of the balloon being in communication with the second lumen. A plug is provided in the first lumen in a region which is spaced away from the balloon towards the proximal extremity of the flexible elongate tubular member. A notch is formed in the elongate flexible tubular member in the plug so that it opens up into the first lumen in the side of the plug proximal to the balloon. A guide wire is adapted to extend through the notch and through the first lumen so that it extends through the balloon and beyond the distal extremity of the balloon. The guide wire also extends rearwardly from the notch along the outside of the flexible tubular member beyond the proximal extremity of the flexible elongate tubular member. If desired, the proximal extremity of the flexible elongate tubular member can be reinforced by placing a mandrel of a suitable material such as metal in the first lumen from the proximal extremity of the flexible tubular member up to the plug in the first lumen.

More in particular, as shown in the drawings, the reinforced balloon dilatation exchange catheter 11 with slitted exchange sleeve consists of a flexible elongate tubular member 12 which is provided with proximal and distal extremities 13 and 14 and which has first and second lumens 16 and 17 extending therethrough. The lumen 16 serves as a guide wire lumen whereas the lumen 17 serves as the balloon inflation lumen. As can be seen, the tubular member 12 in effect provides a dual lumen shaft. In order to achieve the desirable stiffness for the shaft, the tubular member 12 is formed so that it has varying degrees of stiffness with decreasing stiffness towards the distal extremity of the same. The tubular member 12 can be formed of a suitable material such as a polyolefin of various densities. By way of example, assuming that the tubular member 12 has a suitable length, as for example 135 centimeters, the first portion 12a of the tubular member 12 of a length of 105 centimeters from the proximal end can be extruded from a polyolefin compound having a high percentage of high density material, possibly even 100%, with an outside diameter of approximately 1.25 mm (.050 inch) and with dual lumen or first and second lumens 16 and 17 having suitable dimensions as, for example, 0.5 mm (.02 inch) for the first lumen which is to serve as a guide wire lumen and 0.3 mm (.012 inch) for the second lumen which is to serve as a balloon inflation and deflation lumen. In the portion 12b of the tubular member 12 extending beyond the 105 centimeter portion, a for example, the remaining length of the tubular member, the tubular member is reduced to a smaller diameter, as for example, an outside diameter of approximately 1.1 mm (.044 inch) and with the tubular member being extruded of a suitable material such as a mixture of a reduced percentage of high density and an increased percentage of low density polyolefin to provide a tubular member which is more flexible and better able to track the arterial vessel.

The formation of the tubular member 12 of different outside diameters and of materials having different stiffnesses can be readily accomplished by extruding the two portions in separate extrusions using the desired ratio of high density and low density materials. After the extruded portions have been formed, they can be joined together in a suitable manner such as by inserting two mandrels of appropriate sizes through the lumens 16 and 17 from the proximal extremity of the portion formed of a high percentage high density polyolefin and of the portion 12b formed of reduced percentage high density and increased percentage low density polyolefin. After the mandrels (not shown) have been inserted, the abutting extremities of the portions 12a and 12b can be bonded together by suitable means such as by application of heat by the use of a heat gun to abutting extremities of the flexible tubular member. After the bond has been formed, the mandrels can be removed from the proximal extremity of the tubular member. In order to facilitate the heat bonding, a glass mold can be utilized for encasing the abutting extremities of tubular members while the bond is being made.

An inflatable balloon or inflatable balloon means 21 is provided which can have an inflated diameter of a suitable size, as for example,from 1.5 to 4.0 millimeters. The balloon 21 can be formed of a suitable material such as heat shrinkable

polyolefin and is provided with necked down proximal and distal extremities 22 and 23. These proximal and distal extremities 22 and 23 are secured to the distal extremity portion 12c of the tubular member 12 so that the distal extremity of the tubular member 12 is in alignment with the distal extremity of the balloon 21. The proximal and distal extremities 22 and 23 can be secured to the tubular member 12 to form liquid-tight seals in a suitable manner such as by the use of an adhesive, or alternatively, by heat shrinking the same onto the tubular member 12 if the balloon 21 is formed of a heat shrinkable material. The interior 24 of the balloon 21 is in communication with the second lumen 17 through an opening or hole 26 provided in the tubular member 12 within the interior of the balloon.

Radiopaque marker means is provided in the form of radiopaque bands 27 and 28 which are secured to the tubular member 12 within the balloon 21 near the distal and proximal extremities of the balloon. Suitable material such as gold, tungsten or platinum may be utilized for the bands.

The distal portion 12c of the tubular member 12 is formed with a single or first lumen 16 and commences in the region just interiorally of the balloon 21 and can be formed of a suitable compound, such as polyolefin, of an appropriate mixture of high density and low density materials depending on the desired stiffness for this portion of the tubular member. The portion 12c can be bonded to the portion 12b in the manner hereinbefore described for bonding of portions 12b to 12a. By utilizing a single lumen for this portion of the tubular member, it is possible to reduce the outside diameter or profile of the tubular member to a suitable diameter such as 0.73 mm (.029 inch) while retaining an inside diameter of 0.5 mm (.020 inch) for the first lumen 17. This lower profile makes it possible to utilize smaller balloons.

In accordance with the present invention, a plug 31 of a suitable material such as polyolefin is inserted into the first lumen 16 from the distal extremity of the tubular member 12 into a region which is just distal of the junction between the portions 12a and 12b as shown particularly in Figures 1 and 6. This insertion can be accomplished by utilizing a mandrel (not shown) and pushing the plug 31 to the desired position. In order to be able to visually observe the position of the plug 31 in the lumen 16, the plug 31 is preferably formed of a colored material. After the plug 31 has been moved to the desired position, heat is applied to that portion of the tubular member to blend the plug 31 to the inner wall of the tubular member forming the lumen 16 so that the lumen 16 is sealed off or occluded at that point. Alternatively, the plug 31 can be formed by placing two mandrels (not shown) in lumen 16 and providing a space between their innermost ends which approximates the length of the plug 31 desired. Another mandrel (not shown) is placed on the lumen 17 so that it extends through the region of the space between the two spaced apart mandrels in lumen 16. The portion of the tubular member containing the space is heated in a mold so that the plastic material forming the member will melt and flow into the space to form a plug 31 in the lumen 16. After cooling of that portion of the tubular member, the mandrels can be removed. Thereafter, a notch 32 is cut into the tubular member 12 so that it cuts into the distal extremity of the plug 31 and so that an opening is formed into the first lumen 16 distal of the plug 31 which opens exteriorily of the tubular member 12 and also to provide an inclined ramp 33.

If it is desired to provide additional stiffness in the proximal extremity of the tubular member 12, a mandrel 34 such as shown in Figure 7 can be inserted into the portion of the lumen 16 proximal of the plug 31 to serve as a stiffener. The mandrel 34 can have suitable dimensions, as for example, a portion 34a continuous diameter of approximately 0.5 mm (.020 inch) for approximately 98 centimeters of its length from its proximal extremity with a distal portion 34b having a continuous taper of 10 centimeters tapering down to a final dimension of approximately 0.3 mm (.012 inch). When such a mandrel 34 is utilized, the mandrel can be utilized for properly positioning the plug 31 in the first lumen 16 and can be left in place to serve as the stiffener. The mandrel 34 can be formed of a suitable material such as stainless steel. If the mandrel is to be used as a stiffener it is advised to flatten approximately 1 centimeter of the distal tip of the mandrel 34 and locate this portion within the plug to secure the mandrel in place.

The sidewall of the tubular member 12 distal of the notch 32 is provided with a slit 36 extending longitudinally of the tubular member to a location which is approximately .5 to 1 centimeters from the proximal extremity of the balloon 21. This slit 36 extends down into the first lumen 16 throughout this portion of the tubular member 12.

A single lumen Luer-type adapter 38 is mounted on the proximal extremity of the tubular member 12 and is in communication with the second lumen 17.

A guide wire 41 of a suitable type such as the .018 "Hi-Torque Floppy" guide wire manufactured and sold by Advanced Cardiovascular Systems, Inc. of Santa Clara, California is utilized and can be inserted into the catheter 11 by taking the proximal extremity of the guide wire 41 and threading it into the first lumen 16 opening through the distal extremity of the catheter 11 and advancing it towards the proximal extremity of the catheter 11 until it

engages the ramp 33 of the plug 31 and is ramped out through the notch 32. The guide wire 11 can then be grasped and pulled so that it extends longitudinally of the remaining portion of the tubular member 12 and so that it extends beyond the fitting 38.

Visual marking means is provided for locating the relative positions of a balloon dilatation catheter 11 of the present invention in a guiding catheter. For example, a proximal marker 46 can be placed at a suitable distance, as for example, 106 centimeters from the distal tip of the catheter 11 to indicate in an angioplasty procedure when the distal tip of the dilatation catheter is at the distal tip of a guiding catheter. The marker 46 can be in the form of a thin sleeve, approximately .5 centimeters in length, of irradiated, colored 100% low density polyethylene. The sleeve forming the marker 46 can be heat shrunk onto the tubular member 12 as shown in Figure 1. A similar marker 47 can be provided on the tubular member 12 just proximal of the notch 32 as shown in Figure 1.

Operation and use of the balloon dilatation catheter 11 hereinbefore described may now be briefly described as follows. The guiding catheter is first inserted into the vessel of the patient. Thereafter, a balloon dilatation catheter 11 of the present invention of the appropriate size is selected and a guide wire 41 is introduced therein as hereinbefore described. The catheter 11 with its guide wire 41 can then be introduced into the guiding catheter in a conventional manner by first advancing the guide wire into the stenosis and thereafter advancing the balloon dilatation catheter so that the balloon 21 is in the stenosis. By providing a catheter shaft which is formed of various densities of a suitable material such as polyolefin and also by providing the mandrel-type stiffener 34 in the proximal extremity of the tubular member 12, the desired amount of stiffness can be readily obtained to achieve the desired pushability so that the catheter can be readily pushed, or advanced, into the desired location in the stenosis. In such a procedure it should be appreciated that the notch 32 is always positioned within the guiding catheter as is the portion of the guide wire outside of and free of the catheter 11 extending proximally of the notch 32 except where the catheter 11 extends out of the guiding catheter. Thus, the guide wire 41 and the notch 32 will never be outside of the guiding catheter during an angioplasty procedure.

Now let it be assumed that it is desired to exchange the dilatation catheter herein described for a different dilatation catheter, as for example, one having a smaller balloon or alternatively a larger balloon. When this is the case, the guide wire 41 is retained in its position in the stenosis and the balloon dilatation catheter is removed by withdrawing the same until the notch 32 appears outside of the guiding catheter. Thereafter as the catheter 11 is withdrawn, the guide wire can be pulled out through the slit 36 until the catheter has been withdrawn into a point which is just proximal of the balloon 21. Thereafter, the catheter 11 can be withdrawn on the guide wire 41 until the balloon 21 clears the rotating hemostasis valve which is attached to the proximal end of the guiding catheter.

The catheter 11 is then removed from the guide wire. The other catheter which is desired to be used can be threaded onto the distal extremity of the guide wire 41 and then advanced through the rotating hemostasis valve over the guide wire which is still in position into the stenosis to accomplish a further dilatation in a conventional manner.

With this procedure it can be seen that it has been possible to accomplish a rapid exchange of a dilatation catheter by merely making the exchange over a very short length, such as 3 centimeters of the guide wire. Thus with a catheter of the present invention it is possible to utilize conventional guide wires without the necessity for long exchange wires as has been the practice in the past. In addition, it has been possible to accomplish such an exchange utilizing a balloon dilatation catheter which still has the desired amount of stiffness to make it pushable into a remote stenosis.

It should be appreciated that in the present invention a slitted sleeve has been provided which reduces the distance over which an exchange must be accomplished.

Claims

1. A balloon dilatation catheter adapted to be utilized with a guide wire (41), comprising: a flexible elongate tubular member (12) having proximal and distal portions, a lumen (17) extending through said tubular member (12); an inflatable balloon (21) at the distal portion of said tubular member (12), the interior of said inflatable balloon (21) being in communication with said lumen (17); and a sleeve-like means adapted to receive said guide wire (41) therethrough, said sleeve-like means having a proximal opening (32) and said sleeve-like means extending through said balloon (21) to a distal opening at the distal extremity of said tubular member (12), said catheter characterized by the proximal opening of said sleeve-like means (16) being spaced from the proximal end of the catheter and the sleeve-like means (16) having a slit (36) extending longitudinally from the proximal opening of the sleeve-like means (16)

to a region adjacent the balloon (21) to facilitate removal of the guide wire (41) therethrough.

2. A catheter as claimed in Claim 1, characterized in that said sleeve-like means (16) is in the form of an additional lumen provided in the tubular member (12).

3. A catheter as claimed in Claims 1 or 2, characterized in that said tubular member (12) has a portion (12a) thereof formed of a higher density material than other portions (12b) of said tubular member to provide different stiffnesses for said tubular member.

4. A catheter as claimed in Claims 1, 2 or 3, characterized by a stiffening means (34) disposed in the proximal extremity of said tubular member (12) in the portion thereof along which said guide wire (41) is adapted to extend exteriorally of the tubular member (12).

5. A catheter as claimed in Claim 4, characterized in that said stiffening means is in the form of an additional member (34) formed within the tubular member.

6. A catheter as claimed in Claim 5, characterized in that said stiffening means is in the form of a mandrel (34), at least a portion of which is tapered.

7. A catheter as claimed in Claims 1, 2, 3, 4, 5 or 6, characterized by visual marking means (46) and (47) carried by the tubular member.

8. A catheter as claimed in Claim 6, characterized in that said marking means (27) and (28) are colored.

9. A balloon dilatation catheter for use with a guide wire (41) which is adapted to be inserted into a vessel of a patient, comprising: a flexible elongate tubular member (12) having proximal and distal portions and having a first lumen (16) and a second lumen (17) extending therethrough; and a balloon (21) carried by the distal portion of said tubular member (12) and having its interior in communication with said second lumen (17), characterized by said tubular member (12) being provided with a notch (32) which extends from the exterior of said tubular member (12) into said first lumen (16), said notch (32) being positioned proximally of said balloon (21), said guide wire (41) extending through said notch (32) and into said first lumen (16) and through the distal extremity of said tubular member (12) and extending proximally from said notch (32) alongside said tubular member (12) beyond the proximal extremity of said tubular member (12).

10. A catheter as claimed in Claim 9, characterized by plug means (31) disposed in said first lumen (16) proximal of said notch (32) which serves as a ramp to urge said guide wire (41) out of said notch (32) when said guide wire (41) is threaded into said first lumen (16) from the distal extremity of said tubular member (12).

11. A catheter as claimed in Claims 9 or 10, characterized by stiffener means (34) located in said first lumen (16) disposed from the proximal extremity of said tubular member (12) it a region adjacent said notch (32).

12. A catheter as claimed in Claims 9, 10 or 11, characterized in that said tubular member (12) is provided with a slit (36) extending longitudinally of said tubular member (12) from said notch (32) into a region adjacent said balloon (21).

13. A catheter as claimed in Claims 9, 10, 11 or 12, characterized in that said tubular member (12) is formed of a plastic of high and low densities and portions of said tubular member (12) have different proportions of high density and low density plastics so as to provide varying degrees of stiffness along the length of said tubular member (12).

14. A catheter as claimed in Claim 13, characterized in that the proximal extremity of said tubular member (12) is formed of 100% high density plastic.

15. A catheter as claimed in Claim 14, characterized in that an intermediate portion of said tubular member (12) is formed of a mixture of high density plastic and low density plastic.

16. A catheter as claimed in Claims 11, 12, 13, 14 or 15, characterized in that said stiffener (34) is in the form of a mandrel disposed in said first lumen (16).

17. A catheter as claimed in Claims 16, characterized in that the distal extremity (34b) of said mandrel (34) is tapered to vary the stiffness provided by said mandrel.

18. A catheter as claimed in Claim 17, characterized in that said mandrel (34) is formed of a metal.

19. A catheter as claimed in any one of Claims 9-18 characterized by colored visual marker means (46) and (47) carried by said tubular member (12).

Revendications

1. Cathéter de dilatation à ballon, destiné à être utilisé avec un fil de guidage (41), comprenant un organe tubulaire flexible allongé (12) ayant des parties proximale et distale, une lumière (17) étant disposée dans l'organe tubulaire (12), un ballon gonflable (21) placé à la partie distale de l'organe tubulaire (12), l'intérieur du ballon gonflable (21) étant en communication avec la lumière (17), et un dispositif analogue à un manchon destiné à loger le fil de guidage (41), ce dispositif analogue à un manchon ayant une ouverture proximale (32) et étant disposé dans le ballon (21) jusqu'à une ouverture distale qui se trouve à l'extrémité distale de l'organe tubulaire (12), le cathéter étant caractérisé en ce que l'ouverture proximale du dispositif (16) analogue à un manchon est placée à distance de l'extrémité proximale du cathéter, et le dispositif analogue à un manchon (16) a une fente (36) disposée longitudinalement depuis l'ouverture proximale du dispositif (16) analogue à un manchon jusqu'à une région adjacente au ballon (21) afin que l'extraction du fil de guidage (41) soit facilitée.

2. Cathéter selon la revendication 1, caractérisé en ce que le dispositif (16) analogue à un manchon est sous forme d'une lumière supplémentaire disposée dans l'organe tubulaire (12).

3. Cathéter selon l'une des revendications 1 et 2, caractérisé en ce que l'organe tubulaire (12) a une partie (12a) formée d'un matériau de masse volumique accrue par rapport aux autres parties (12b) de l'organe tubulaire, afin que l'organe tubulaire ait des rigidités différentes.

4. Cathéter selon la revendication 1, 2 ou 3, caractérisé par un dispositif de renforcement (34) placé dans l'extrémité proximale de l'organe tubulaire (12) dans sa partie le long de laquelle le fil de guidage (41) est destiné à être placé à l'extérieur de l'organe tubulaire (12).

5. Cathéter selon la revendication 4, caractérisé en ce que le dispositif de renforcement est sous forme d'un organe supplémentaire (34) formé dans l'organe tubulaire.

6. Cathéter selon la revendication 5, caractérisé en ce que le dispositif de renforcement est sous forme d'un mandrin (34) dont une partie au moins est tronconique.

7. Cathéter selon la revendication 1, 2, 3, 4, 5 ou 6, caractérisé par un dispositif de marquage visuel (46 et 47) porté par l'organe tubulaire.

8. Cathéter selon la revendication 6, caractérisé en ce que le dispositif de marquage (27 et 28) est coloré.

9. Cathéter de dilatation à ballon destiné à être utilisé avec un fil de guidage (41) qui est destine à être introduit dans un vaisseau d'un patient, comprenant un organe tubulaire flexible allongé (12) ayant des parties proximale et distale et ayant une première lumière (16) et une seconde lumière (17) formées à l'intérieur, et un ballon (21) porté par la partie distale de l'organe tubulaire (12) et dont l'intérieur communique avec la seconde lumière (17), caractérisé en ce que l'organe tubulaire (12) a une encoche (32) partant de l'extérieur de l'organe tubulaire (12) et pénétrant dans la première lumière (16), l'encoche (32) étant placée vers l'intérieur par rapport au ballon (21), le fil de guidage (41) passant dans l'encoche (32), pénétrant dans la première lumière (16) et passant dans l'extrémité distale de l'organe tubulaire (12), et étant aussi disposé vers l'intérieur à partir de l'encoche (32), le long de l'organe tubulaire (12) et au-delà de l'extrémité proximale de l'organe tubulaire (12).

10. Cathéter selon la revendication 9, caractérisé par un bouchon (31) placé dans la première lumière (16) près de l'encoche (32) et utilisé comme rampe de manière qu'il repousse le fil de guidage (41) en dehors de l'encoche (32) lorsque le fil de guidage (41) est enfilé dans la première lumière (16) par l'extrémité distale de l'organe tubulaire (12).

11. Cathéter selon la revendication 9 ou 10, caractérisé par un organe de renforcement (34) placé dans la première lumière (16) depuis l'extrémité proximale de l'organe tubulaire (12) jusqu'à une région adjacente à l'encoche (32).

12. Cathéter selon la revendication 9, 10 ou 11, caractérisé en ce que l'organe tubulaire (12) a une fente (36) disposée suivant la longueur de l'organe tubulaire (12) depuis l'encoche (32) dans une région adjacente au ballon (21).

13. Cathéter selon la revendication 9, 10, 11 ou 12, caractérisé en ce que l'organe tubulaire (12) est formé d'une matière plastique ayant des masses volumiques élevée et faible, et des parties de l'organe tubulaire (12) ont des proportions différentes des matières plastiques de masses volumiques élevée et faible afin que divers degrés de rigidité soient obtenus le long de l'organe tubulaire (12).

14. Cathéter selon la revendication 13, caractérisé en ce que l'extrémité proximale de l'organe tubulaire (12) est formée à 100 % d'une matière plastique de masse volumique élevée.

15. Cathéter selon la revendication 14, caractérisé en ce qu'une partie intermédiaire de l'organe tubulaire (12) est formée d'un mélange d'une matière plastique de masse volumique élevée et d'une matière plastique de faible masse volumique.

16. Cathéter selon la revendication 11, 12, 13, 14 ou 15, caractérisé en ce que l'organe de renforcement (34) est sous forme d'un mandrin disposé dans la première lumière (16).

17. Cathéter selon la revendication 16, caractérisé en ce que l'extrémité distale (34b) du mandrin (34) est tronconique afin que la rigidité donnée par le mandrin varie.

18. Cathéter selon la revendication 17, caractérisé en ce que le mandrin (34) est formé d'un métal.

19. Cathéter selon l'une quelconque des revendications 9 à 18, caractérisé par un dispositif coloré de marquage visuel (46 et 47) porté par l'organe tubulaire (12).

Patentansprüche

1. Ballondilatationskatheter, welcher mit einem Führungsdraht (41) verwendet werden kann, umfassend: ein biegsames, längliches rohrförmiges Element (12) mit proximalen und distalen Abschnitten, wobei sich ein Lumen (17) durch das rohrförmige Element (12) erstreckt; einen aufblasbaren Ballon (21) an dem distalen Abschnitt des rohrförmigen Elementes (12), wobei das Innere des aufblasbaren Ballons (21) mit dem Lumen (17) in Verbindung steht; und eine hülsenartige Einrichtung, die den Führungsdraht (41) aufnehmen kann, wobei die hülsenartige Einrichtung eine proximale Öffnung (32) aufweist und die hülsenartige Einrichtung sich durch den Ballon (21) bis zu einer distalen Öffnung am distalen Ende des rohrförmigen Elementes (12) erstreckt, wobei der Katheter dadurch gekennzeichnet ist, daß die proximale Öffnung der hülsenartigen Einrichtung (16) im Abstand von dem proximalen Ende des Katheters angeordnet ist, und die hülsenartige Einrichtung (16) einen Schlitz (36) aufweist, der sich in Längsrichtung von der proximalen Öffnung der hülsenartigen Einrichtung (16) zu einem Bereich in der Nähe des Ballons (21) erstreckt, um das Entfernen des Führungsdrahtes (41) durch den Schlitz hindurch zu erleichtern.

2. Katheter nach Anspruch 1, dadurch gekennzeichnet, daß die hülsenartige Einrichtung (16) in Form eines zusätzlichen Lumens vorliegt, welches in dem rohrförmigen Element (12) vorgesehen ist.

3. Katheter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß das rohrförmige Element (12) einen Abschnitt (12a) aufweist, welcher aus einem Material mit höherer Dichte gebildet ist als andere Abschnitte (12b) des rohrförmigen Elementes, um das rohrförmige Element mit unterschiedlichen Steifigkeiten zu versehen.

4. Katheter nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, daß eine Versteifungseinrichtung (34) in dem proximalen Ende des rohrförmigen Elementes (12) in dem Abschnitt vorgesehen ist, entlang dem sich der Führungsdraht (41) außerhalb des rohrförmigen Elementes (12) erstrecken kann.

5. Katheter nach Anspruch 4, dadurch gekennzeichnet, daß die Versteifungseinrichtung in Form eines zusätzlichen Elementes (34) vorliegt, welches in dem rohrförmigen Element ausgebildet ist.

6. Katheter nach Anspruch 5, dadurch gekennzeichnet, daß die Versteifungseinrichtung in Form einer Spindel (34) vorliegt, die mindestens in einem Abschnitt verjüngt ist.

7. Katheter nach Anspruch 1, 2, 3, 4, 5 oder 6, gekennzeichnet durch optische Markierungseinrichtungen (46) und (47), welche auf dem rohrförmigen Element angebracht sind.

8. Katheter nach Anspruch 6, dadurch gekennzeichnet, daß die Markierungseinrichtungen (27) und (28) farbig sind.

9. Ballondilatationskatheter zur Verwendung mit einem Führungsdraht (41), welcher in ein Gefäß eines Patienten eingeführt werden kann, umfassend: ein biegsames, längliches rohrförmiges Element (12) mit proximalen und distalen Abschnitten und mit einem ersten Lumen (16) und einem zweiten Lumen (17), welches sich durch dieses Element hindurch erstreckt; und einen Ballon (21), der auf dem distalen Abschnitt des rohrförmigen Elementes (12) angebracht ist, und dessen Inneres mit dem zweiten Lumen (17) in Verbindung steht, dadurch gekennzeichnet, daß das rohrförmige Element (12) mit einer Kerbe (32) versehen ist, die sich von der Außenseite des rohrförmigen Elementes (12) in das erste Lumen (16) erstreckt, wobei die Kerbe (32) proximal von dem Ballon (21) angeordnet ist, und der Führungsdraht (41) erstreckt sich durch die Kerbe (32) und in das erste Lumen (16) und durch das distale Ende des rohrförmigen Elementes (12), und er erstreckt sich proximal von der Kerbe (32) entlang dem rohrförmigen Element (12) bis über das proximale Ende des rohrförmigen Elementes (12).

10. Katheter nach Anspruch 9, dadurch gekennzeichnet, daß ein Stöpsel (31) in dem ersten Lumen (16) proximal von der Kerbe (32) angeordnet ist, welcher als Anschlag dient, um den Führungsdraht (41) aus der Kerbe (32) zu drücken, wenn der Führungsdraht (41) vom distalen Ende des rohrförmigen Elementes (12) aus in das erste Lumen (16) eingefädelt wird.

11. Katheter nach Anspruch 9 oder 10, gekennzeichnet durch eine in dem ersten Lumen (16) vorgesehene Versteifungseinrichtung (34), welche im Abstand von dem proximalen Ende des rohrförmigen Elementes (12) in einem Bereich in der Nähe der Kerbe (32) angeordnet ist.

12. Katheter nach Anspruch 9, 10 oder 11, dadurch gekennzeichnet, daß das rohrförmige Element (12) mit einem Schlitz (36) versehen ist, der sich in Längsrichtung des rohrförmigen Elementes (12) von der Kerbe (32) in einen Bereich in der Nähe des Ballons (21) erstreckt.

13. Katheter nach Anspruch 9, 10, 11 oder 12, dadurch gekennzeichnet, daß das rohrförmige Element (12) aus einem Kunststoff hoher und niedriger Dichte gebildet ist, und daß Abschnitte des rohrförmigen Elementes (12) unterschiedliche Anteile von Kunststoffen hoher und niedriger Dichte aufweisen, um verschiedene Grade von Steifigkeit auf der Länge des rohrförmigen Elementes (12) zu erzeugen.

14. Katheter nach Anspruch 13, dadurch gekennzeichnet, daß das proximale Ende des rohrförmigen Elementes (12) aus 100% hochdichtem Kunststoff gebildet ist.

15. Katheter nach Anspruch 14, dadurch gekennzeichnet, daß ein Zwischenstück des rohrförmigen Elementes (12) aus einer Mischung aus Kunststoff hoher Dichte und Kunststoff niedriger Dichte gebildet ist.

16. Katheter nach Anspruch 11, 12, 13, 14 oder 15, dadurch gekennzeichnet, daß die Versteifungseinrichtung (34) in Form einer Spindel vorliegt, welche in dem ersten Lumen (16) angeordnet ist.

17. Katheter nach Anspruch 16, dadurch gekennzeichnet, daß das distale Ende (34b) der Spindel (34) verjüngt ist, um die durch die Spindel bewirkte Steifigkeit zu verändern.

18. Kathether nach Anspruch 17, dadurch gekennzeichnet, daß die Spindel (34) aus einem Metall besteht.

19. Katheter nach einem der Ansprüche 9 - 18, gekennzeichnet durch farbige optische Markierungseinrichtungen (46) und (47), die auf dem rohrförmigen Element (12) angebracht sind.

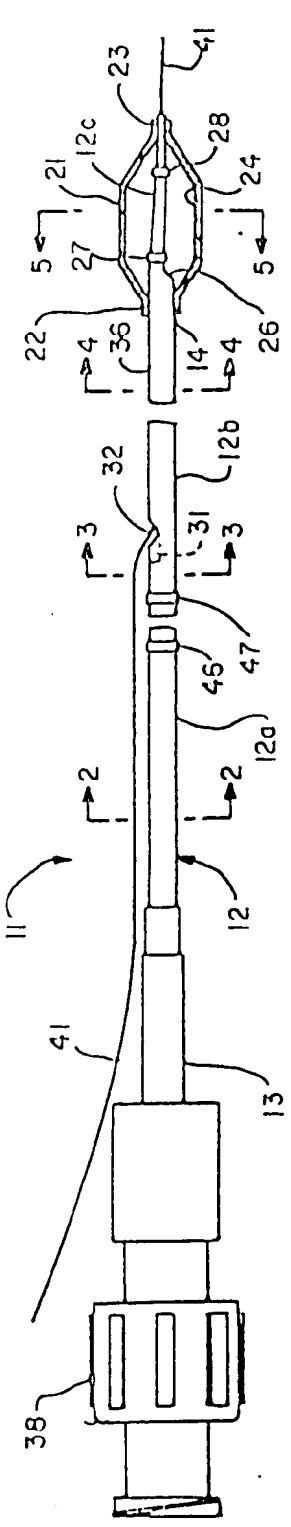

FIG. -1

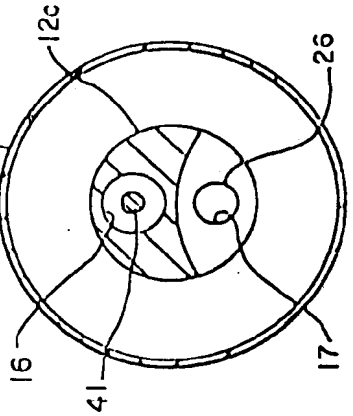

FIG. -5

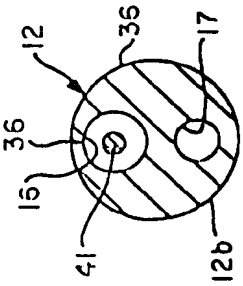

FIG. -4

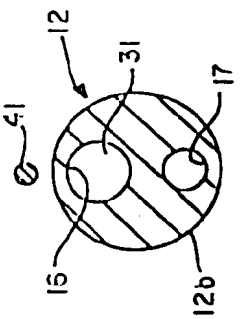

FIG. -3

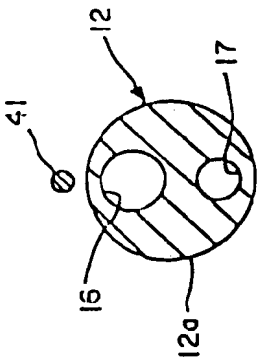

FIG. -2

FIG. -7

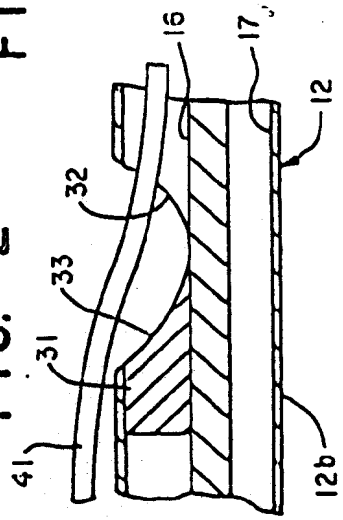

FIG. -6